

REMARKS/ARGUMENTS

Upon entry of this amendment, claims 40, 41, 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 76, 78, 80, 81, 88, 93, 123-128, 130, and 140 will be pending in the application. Claims 1-39, 42-44, 46, 48-53, 55, 58, 60, 61, 64-67, 69, 71-75, 77, 79, 82-87, 89-92, 94-122, 129, and 131-139 have been canceled without prejudice to prosecution thereof at a later date. Claims 40 and 41 have been allowed. Claims 45, 47, 54, 56, 57, 59, 62, 63, 70, 76, 78, 80, 81, 88, 93, 123-126, and 130 have been amended without introducing new matter. New claim 140 corresponds to claim 63.

Preliminarily, Applicants note with appreciation the rejoinder of claims 81, 84-91, 93, 123-128, 130, and 139 and withdrawal of a number of the previous rejections. Applicants further note with appreciation acknowledgment of consideration of the references listed in the Supplemental Information Disclosure Statement submitted February 26, 2003.

I. Claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 76, 78, 80, 81, 88, 93, 123-128, and 130 as amended satisfy the requirements of the second paragraph of 35 U.S.C. § 112.

Claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 72, 75, 76, 78, 80-91, 93, 123-128, and 130 are rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness. Claims 72, 75, 82-87, and 89-91 have been canceled without prejudice. Although Applicants do not concur in the rejection, the remaining solicited claims have been amended in an effort to advance prosecution of the application.

Claims 45, 47, 56, 62, 76, 78, 80, 81, and 93 are amended herein to clarify that SEQ ID NO:5 is an amino acid sequence. Similarly, claims 123-125 and 130 are amended herein to reflect that SEQ ID NO:4 is a nucleotide sequence.

Claims 45, 54, 62, 78, 81, and 126 are amended herein to omit reference to "CAI."

Applicants respectfully assert that one of ordinary skill in the art would understand the metes and bounds of the invention conveyed by claims 45, 54, 62, and 78 in view of recitation of "at least" with respect to the number of amino acid residues in each claimed polypeptide. For example, a polypeptide having at least five amino acids includes a polypeptide having 12 residues.

Applicants respectfully assert that the claims as amended do not recite the phrase "immunologically identifiable" or "immunogenically identifiable."

Applicants respectfully submit that the claims as amended satisfy 35 U.S.C. § 112, second paragraph and request withdrawal of the rejection.

II. Claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 76, 78, 80, 81, 88, and 93 do not contain new matter.

Claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 75, 76, 78, 80-91, and 93 are rejected for alleged recitation of new matter. Applicants traverse the rejection. Preliminarily, Applicants note that claims 75, 82-87, and 89-91 have been canceled.

Claims 45, 54, 57, 62, 63, 70, 78, and 81 are rejected for alleged recitation of new matter with respect to the phrase "immunologically identifiable by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen" or cytotoxin or heat shock protein.

Applicants traverse the rejection in view of the support for the alleged new matter located in the specification, for example, at page 14, lines 21-30 (including within the definition of "polypeptide" as used in the specification "immunologically identifiable" polypeptides) and at page 51, line 30 to page 52, line 14 (describing the production of antibodies to polypeptides comprising portions of CAI antigen). Nonetheless, in an effort to advance

prosecution of the application, Applicants have amended the claims to omit the phrase “immunologically identifiable.”

Claims 93 and 130 are rejected for alleged recitation of new matter with respect to the phrases “at least five contiguous amino acids from amino acids 707-937 of SEQ ID NO:5” and “at least fifteen contiguous nucleotides of nucleotide positions 2772-3466 of SEQ ID NO:4,” respectively. Applicants have amended claims 93 and 130 to recite amino acids 748-977 of SEQ ID NO:5 and nucleotide positions 2776-3466 of SEQ ID NO:4, respectively. Support for the amendments may be found in the specification, for example, Figures 3 and 4.

Withdrawal of the rejections in view of the amendments is respectfully requested.

III. Claims 57, 59, 63, 70, and 80 are adequately supported by the specification in accordance with 35 U.S.C. § 112, first paragraph.

Claims 57, 59, 63, 70, and 80 are rejected under the first paragraph of 35 U.S.C. § 112 for alleged lack of adequate written descriptive support. Although Applicants disagree with the rejection, claims 57, 59, and 63 have been amended to recite *Helicobacter pylori* heat shock protein having the amino acid sequence of SEQ ID NO:6, and claims 70 and 80 have been amended to recite *Helicobacter pylori* cytotoxin having the amino acid sequence of SEQ ID NO:3.

Applicants respectfully submit that the solicited claims as amended herein are adequately described by the specification. The written description requirement can be met by disclosing functional characteristics coupled with a known or disclosed correlation between function and structure. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002) (citing Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1 “Written Description” Requirement (66 Fed. Reg. 1099, 1106(Jan. 5, 2001))).

Applicants respectfully submit that the present claims, including 5mer, 10mer, and 15mer *Helicobacter pylori* polypeptides, combine functional characteristics (e.g., CAI, hsp, or CT polypeptides and fragments thereof) with a correlation between function and structure (e.g., amino acid sequences of SEQ ID NOs:3, 5, 6 for *Helicobacter pylori* CT, CAI, and hsp polypeptides, respectively) sufficient to satisfy the written description requirement. Moreover, the specification includes multiple examples of polypeptide fragments of the invention that satisfy the claims. *See, e.g.*, Specification at page 45, line 25 to page 46, line 6 and page 47, lines 18-23 (describing the preparation of antisera against a CT fragment fusion protein); page 52, lines 8-14 (describing specific antisera against CAI antigen fusion proteins); and page 56, line 28 to page 57, line 1 (describing antisera production against *Helicobacter pylori* hsp fusion proteins). Applicants respectfully submit that the solicited claims satisfy the written description requirement of section 112 in view of the correlation between structure and function in the claims and the inclusion of examples in the specification.

Accordingly, Applicants respectfully request withdrawal of the rejection.

IV. Claim 81 is patentable over U.S. Patent No. 5,541,291 to Keene.

Claim 81 is rejected under 35 U.S.C. § 102(e) for alleged anticipation by U.S. Patent No. 5,541,291 to Keene ("Keene"). Applicants traverse the rejection.

To anticipate a claim, a prior art reference must teach, either expressly or inherently, each and every element of the claim. *See Verdegaa Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Claim 81 as amended herein is directed to isolated immunogenic polypeptides having at least five contiguous amino acids from the *Helicobacter pylori* CAI antigen having the amino acid sequence of SEQ ID NO:5, wherein the polypeptide comprises at least one of the amino acid sequences of SEQ ID NO:9, SEQ ID NO:10, or six asparagines residues.

Keene describes an antigen comprising the amino acid sequence LKERQEAEK that is reactive with autoantibodies associated with an autoimmune disease. Keene does not teach a *Helicobacter pylori* CAI antigen fragment having SEQ ID NO:9, SEQ ID NO:10, or six asparagines as presented in amended claim 81. Accordingly, Applicants request that the rejection be withdrawn.

V. The solicited claims are patentable over the Peterson reference.

Claim 139 is rejected under 35 U.S.C. § 102(b) for alleged anticipation by Peterson *et al.* (*Nature*, 354:369-373 (1991)). Applicants have canceled claim 139 and request withdrawal of the rejection.

Applicants further note that claim 81 as amended herein recites isolated immunogenic polypeptides having at least five amino acids of the *Helicobacter pylori* CAI antigen having the amino acid sequence of SEQ ID NO:5, including the amino acid sequence of SEQ ID NO:9, 10, or six asparagines. Applicants respectfully assert that amended claim 81 is patentably distinct over the disclosure of the Peterson reference relating to a transcription factor TFIIE having SEQ ID NO:10.

VI. Claims 45, 47, 54, 56, 62, 68, 78, 81-86, 88-91, 93, 123-126, 128, and 130 are patentable over U.S. Patent No. 5,403,924 to Cover et al.

Claims 45, 47, 54, 56, 62, 68, 75, 76, 78, 81-86, 88-91, 93, 123-126, 128, and 130 are rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 5,403,924 to Cover *et al.* ("Cover"). Applicants traverse the rejection. Preliminarily, Applicants note that claims 75, 76, 82-86, and 89-91 have been canceled without prejudice.

Applicants respectfully assert that Applicants have priority over Cover as to *Helicobacter pylori* CAI antigen having SEQ ID NO:9, SEQ ID NO:10, or six asparagines. While the Cover patent teaches an amino acid sequence having EFKNGKNKDFSK, EPIYA, or NNNNNN, Applicants respectfully submit that Applicants have priority as to these sequences. Applicants disclosed amino acids 3-12 of SEQ ID NO:9, SEQ ID NO:10, and the six asparagine stretch in their Italian priority document filed March 2, 1992. *See, e.g.*, Claim 2 of Italian Application Serial No. FI/92/A/52 (previously submitted). These sequences were added to the Cover patent with its April 26, 1993 submission. Accordingly, Applicants request withdrawal of the rejection.

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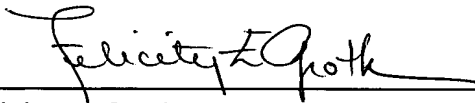
CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a Notice of Allowance at an early date is respectfully requested

If the Examiner believes a telephone conference would expedite prosecution of this application, the undersigned may be contacted at 215-557-5908.

Respectfully submitted,

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Felicity E. Groth
Registration No. 47,042

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439